



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/677,633	10/02/2003	Jeffrey C. Cerier	100873-283 END6430USCIP5	4181
81353 7590 09/10/2008 Ethicon Endo-Surgery/Nutter, McClennen & Fish LLP World Trade Center West 155 Seaport Blvd. Boston, MA 02210-2604			EXAMINER WOO, JULIAN W	
			ART UNIT 3773	PAPER NUMBER
			NOTIFICATION DATE 09/10/2008	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

Office Action Summary	Application No. 10/677,633	Applicant(s) CERIER, JEFFREY C.	
	Examiner Julian W. Woo	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8/7/08.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-28 and 41-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-28 and 41-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) ☒ Notice of References Cited (PTO-892) | 4) ☐ Interview Summary (PTO-413) |
| 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) ☒ Information Disclosure Statement(s) (PTO/SB/08) | 5) ☐ Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/16/08</u> . | 6) ☐ Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 16, 2008 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 11-13 and 22-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Richards et al. (4,669,473). Richards et al. disclose, at least in figures 10-14 and col. 6, line 20 to col. 9, line 23; a tissue fixation device including a suture (e.g., 310), a first biocompatible securing element (315) connected to a first portion of the suture, a second biocompatible securing element (316) connected to a second portion of suture, each of the first and second securing elements being rotatable from a first position during deployment and a second position when deployed, and a deployment instrument with first and second tubes (405, 406), where the first and second securing elements are spaced apart from a third portion of suture (see fig. 13),

Art Unit: 3773

where a portion of the suture is coupled to another portion of the suture by knotting (see col. 5, lines 50-55 and col. 6, lines 20-22), where the first and second securing elements are generally cylindrical in shape, and are oriented at least substantially parallel to holes in the first position and are oriented at least substantially perpendicular to the holes in the tissue in the second position, and where the first and second securing elements each include a sharp tip and an elongated shape, such that a long axis is larger than a diameter of a tissue hole.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 7-10, 18-21, and 41-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richards et al. (4,669,473) in view of McQuilkin et al. (5,219,359). Richards et al. disclose the invention substantially as claimed. Richards et al. disclose,

Art Unit: 3773

at least in figures 8-10 and col. 6, lines 6-64; a tissue fixation device including a suture (10B or 310), a first biocompatible or bioimplantable pledget (40B) having at least one through hole, a first portion of the suture (10B) passing through the at least one through hole, a first biocompatible securing element 15B or 315) connected to a portion of the suture, the first securing element being rotatable from a first orientation to second orientation as claimed, where the suture and the first pledget are effective to fix adjacent layer of tissue, where the device includes a second suture (310, see col. 6, lines 20-22) and a second biocompatible securing element (316) connected to a second portion of the suture and rotatable from first and second positions as claimed, and where the sutures and the first and second securing elements comprise biocompatible materials (see col. 6, lines 46-64). However, Richards et al. do not disclose a second bioimplantable or bioimplantable pledget having at least one through hole, where a first portion of the second suture passes through a second through hole in the first pledget or where two end of suture are passed through through holes of the first and second pledgets, where both ends are disposed on the same side of the first pledget.

McQuilkin et al. teach, at least in the figures, first and second bioimplantable pledgets (30, 32) each including a plurality of through holes for receiving first and second suture portions or ends (24, 22). It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of McQuilkin et al., to include first and second bioimplantable pledgets as claimed with the suture or suture portions and securing elements of Richards et al. Such modifications would allow the device of

Art Unit: 3773

Richards et al. to effectively clamp and/or support organ tissue without undue tissue damage, as exemplified in figures 10-12.

6. Claim 15 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Richards et al. (4,669,473).

Richards et al. disclose, at least in col. 5, lines 50-55 and col. 6, lines 20-22, suture portions coupled together, but do not specifically disclose welding of the suture portions. Nevertheless, claim 15 is construed as a product-by-process claim, and the product (suture) does not depend on the process of making it. The claimed product appears to be the same as the suture of Richards et al. Thus, the suture of Richards et al. anticipates or is obvious over the claimed (welded) suture.

7. Claims 16, 17, 27, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richards et al. (4,669,473) in view of Bonutti (5,845,645). Richards et al. disclose the invention substantially as claimed. Richards et al. disclose, in col. 11, lines 22-26; securing elements separably attachable to suture portions, which in turn, are coupled together. However, Richards et al. do not disclose suture portions passing through openings in the first and second securing elements and suture that is endless or forms a closed loop. Bonutti teaches, at least in figure 6 and col. 3, lines 22-29; a securing element (20) including through openings (40, 42) for receiving two legs (48, 50) of suture configured to be coupled to tissue or other devices. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Bonutti, to modify the securing elements and suture portions of Richards et al., so that securing elements include through openings and so that the suture portions

Art Unit: 3773

comprise suture legs coupled together to form an endless suture or a closed loop. Such modifications would allow the securing elements to be positively rotated and secured within tissue by suture legs, while suture legs coupled to other suture legs (to form an endless suture or closed loop) would allow doubling of the suture used to hold tissue and ensure that the tissue is held or anchored with less risk of breakage of the tensioned suture.

Response to Amendment

8. Applicant's arguments with respect to claims 7-28 and 41-44 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

Art Unit: 3773

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Julian W. Woo/
Primary Examiner, Art Unit 3773

September 9, 2008